

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The Information Disclosure Statement (IDS) filed 3 June 2010 has been entered.

Applicant's remarks and the Declaration under 37 C. F. R. 1.132 of Dr. Wilfred Germeraad filed 3 June 2010 have been entered.

Claims 10, 11, 14-18, 20, 25 and 26 are cancelled. Claims 1-9, 12, 13, 19 and 21-24 are pending.

### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given in an telephone interview with Attorney Leonard R. Svensson on 13 August 2010.

#### **Please amend the claims as following:**

1. A method for the treatment of a tumor which comprises administering to a patient in need thereof an effective amount of active dendritic cells (DC) that are tumor-specific and secrete IL12, said tumor-specific and IL12-secreting DC being prepared by a process comprising:
  - (a) collecting DC precursor cells from a suitable autologous or allogeneic source to obtain a DC culture;
  - (b) loading the DC of said DC culture with a tumor specific antigen; and
  - (c) exposing said DC culture to a concentration of LPS and a concentration of IFN- $\gamma$  effective to trigger the DC of said DC culture to secrete IL12 to thereby obtain said tumor-specific and IL12-secreting DC, wherein said exposure to LPS and IFN- $\gamma$  occurs over a period of 2-6 hours.

9. The method according to claim 1, wherein the active DC have been generated *in vitro* from peripheral blood mononuclear cells (PBMCs).
19. A method for the treatment of a tumor which comprises administering to a patient in need thereof an effective amount of active dendritic cells (DC) that are tumor-specific and secrete IL12, said tumor-specific and IL12-secreting DC being prepared by a process consisting essentially of:
- (a) collecting DC precursor cells from a suitable autologous or allogeneic source to obtain a DC culture;
  - (b) loading the DC of said DC culture with a tumor specific antigen; and
  - (c) exposing said DC culture to a concentration of LPS and a concentration of IFN- $\gamma$  effective to trigger the DC of said DC culture to secrete IL12 to thereby obtain said tumor-specific and IL12-secreting DC, wherein said exposure to LPS and IFN- $\gamma$  occurs over a period of 2-6 hours.
21. A method for the treatment of a tumor consisting essentially of administering to a patient in need thereof an effective amount of active dendritic cells (DC), and wherein said active DC are prepared by a process consisting essentially of:
- (a) collecting DC precursor cells from a suitable autologous or allogeneic source to obtain a DC culture;
  - (b) loading the DC of said DC culture with a tumor specific antigen; and
  - (c) exposing said DC culture to a concentration of LPS and a concentration of IFN- $\gamma$  effective to trigger the DC of said DC culture to secrete IL12 and thereby obtain said active DC, wherein said exposure to LPS and IFN- $\gamma$  occurs over a period of 2-6 hours.
22. The method of claim 1 wherein said active DC are administered or frozen after exposure to LPS and IFN- $\gamma$ .
23. The method of claim 1 wherein said exposure to LPS and IFN- $\gamma$  occurs over a period of 2 hours.
24. The method of claim 1 wherein said exposure to LPS and IFN- $\gamma$  occurs over a period of 6 hours.

Please cancel claims 12 and 13 without prejudice to Applicant's right to pursue the subject matter therein in a related application.

The following is an examiner's statement of reasons for allowance:

Applicant has provided the Declaration under 37 C. F. R. 1.132 of Dr. Wilfred Germeraad in support that one of skill in the art would not have found the present invention obvious at the time of filing. In the Declaration, the Declarant indicates that the prior art reference (specifically, Kakinshi et al.) does not show a time course of IL-12 production when LPS/IFN- $\gamma$  was applied to immature DC. The Declarant further discusses the state of the art of using active DC in cancer immune therapy, and indicates that prior to Applicant's invention, one of skill in the art could not expect the efficiency of the present therapy. Applicant's arguments and the Germeraad Declaration have been found to be persuasive, which, along with the unexpected results presented in the specification, have been found sufficient to overcome the obviousness rejections remaining in the previous Office action (mailed 3/3/2010).

The amendment to the claims was made to clarify the claimed invention. Claims 12 and 13 are cancelled without prejudice to Applicant's intention to pursue the subject matter therein in continuing applications in a telephonic response received on 13 August 2010.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.  
August 13, 2010

/Elizabeth C. Kemmerer/  
Elizabeth C. Kemmerer, Ph.D.  
Primary Examiner, Art Unit 1646